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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,863	07/06/2000	David Gustafsson	3525-86	4411

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 06/03/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/582,863

Applicant(s)

GUSTAFSSON, DAVID

Examiner

Chih-Min Kam

Art Unit

1653

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 and 31 is/are allowed.
- 6) ☒ Claim(s) 30,32-45 and 50-57 is/are rejected.
- 7) ☒ Claim(s) 21-29,33-40 and 42-57 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. Claims 20-57 are pending.

Applicants' amendment filed on March 26, 2003 (Paper No. 12) is acknowledged, and applicants' response has been fully considered. Claims 25, 32, 34 and 41-43 have been amended, and new claims 44-57 have been added. Thus, claims 20-57 are examined.

#### Rejection Withdrawn

#### *Claim Rejections - 35 USC § 112*

2. The previous rejection of claims 25-30 and 32-43, under 35 U.S.C. § 112, second paragraph, regarding improper dependent claim and the claim lacking recitation of the outcome of the treatment, is withdrawn in view of applicants' amendment to the claims and applicants' response at pages 10-11 in Paper No. 12.

#### *Claim Objection*

3. Claim 21, for example, is objected to because of the use of the term "A kit of parts as claimed in Claim 20". Since claim 21 depends from claim 20, the term "The kit of parts as claimed in Claim 20" should be used. See also claims 22-29, 33-40 and 42-57.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 30, 32-45 and 50-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claim 30 is indefinite because the claim recites the kit contains one of components (a) and (b), and the instructions to use that component with the other of the two components, however, the claim does not indicate the inclusion of the second component in the kit.

6. Claims 32-44 and 54-57 are indefinite because the claims lack an essential step in the method of treating a condition in which inhibition of thrombin is required. The omitted step is the effective amount of pharmaceutical formulations administered. Claims 33-40, 42-44 and 50-57 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

7. Claim 33, for example, recites the limitation "component (a)" and "component (b)" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. See also claims 38-40 and 44.

8. Claims 45 and 50 are indefinite because the claim recites the term "the thrombin inhibitor", it is not clear which thrombin inhibitor is referred to "the thrombin inhibitor", is it the first thrombin inhibitor or the second one?

### ***Conclusion***

9. Claims 30, 32-45 and 50-57 are rejected, and claims 21-29, 33-40 and 42-57 are objected to. It appears that claims 20 and 31 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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May 31, 2003

*Christopher S. F. Low*  
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